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<p>Substitute for form 1449A/PTO</p> <p>SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p>		<p>Complete if Known</p>	
		Application Number	10/633,966
		Filing Date	August 4, 2003
		First Named Inventor	Ekwuribe, Nnochiri N.
		Art Unit	1655 1656
		Examiner Name	Hope A. Robinson
Sheet	1	of	2
		Attorney Docket Number	014811-96.22DV

U.S. PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS

FOREIGN PATENT DOCUMENTS						
Examiner Initials ¹	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ²
		Country Code ³ -Number ⁴ -Kind Code ⁶ (if known)				

Examiner Signature		Date Considered	10/28/05
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***EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO		Complete if Known			
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>		Application Number	10/633,966		
		Filing Date	August 4, 2003		
		First Named Inventor	Ekwuribe, Nnochiri N.		
		Art Unit	4655 1654		
		Examiner Name	Hope A. Robinson		
Sheet	2	of	2	Attorney Docket Number	014811-96.22DV

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
HR	B5	KANG CHOON LEE et al.; Isolation, Characterization, and Stability of Positional Isomers of Mono-PEGylated Salmon Calcitonins; Pharmaceutical Research; 1999; Vol. 16, No. 6, pp. 813-818; Plenum Publishing Corporation		
	B6	HAESHIN LEE et al.; Preparation and Characterization of Mono-PEGylated Epidermal Growth Factor: Evaluation of <i>in Vitro</i> Biologic Activity; Pharmaceutical Research; 2002; Vol. 19, No. 6, pp. 845-851; Plenum Publishing Corporation		
	B7	ANDREA LUCKE et al.; Biodegradable poly(D,L-lactic acid)-poly(ethylene glycol)-monomethyl ether diblock copolymers: structures and surface properties relevant to their use as biomaterials; Biomaterials; 2000; 21, pp. 2361-2370; Elsevier Science Ltd.		
✓	B8	JONG-HOON LEE et al.; Polymeric nanoparticle composed of fatty acids and poly(ethylene glycol) as a drug carrier; International Journal of Pharmaceutics; 2003; 251, pp. 23-32; Elsevier Science B.V.		

Examiner Signature	<i>Hope Robinson</i>	Date Considered	10/28/05
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¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

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FORM PTO-1449		US Dept. of Commerce Patent and Trademark Office	ATTORNEY DOCKET NO. 4012-130-9233-220V	SERIAL NO. to be assigned 09/439,443
INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)		APPLICANT Nnochiri N. Ekwuribe		
		FILING DATE concurrently herewith December 13, 1999		GROUP Not Yet Assigned

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
HAC	AA	5,407,683	18 Apr. 1995	Shively, Merrick L.	424	439	
	AB	5,422,364	6 Jun. 1995	Nicolaou, et al.	514	449	
	AC	5,439,686	8 Aug. 1995	Desai et al.	424	451	
	AD	5,484,809	16 Jan. 1996	Hostetler et al.	514	449	
	AE	5,560,933	1 Oct 1996	Soon-Shiong et al.	424	489	
	AF	5,608,087	4 Mar. 1997	Nicolaou et al.	549	510	
	AG	5,795,909	18 Aug. 1998	Shashoua et al.	514	449	
	AH	5,817,840	6 Oct. 1998	Nicolaou et al.	549	510	
↓	AI	5,932,462	2 Aug. 1999	Harris et al.	435	188	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
AAC	AJ	WO 97/33552	18 Sep. 1997	PCT	—	—		
IV	AK	WO 98/58927	30 Dec. 1998	PCT	—	—		

OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)

HAC	AL	Adams, Jonathan D., et al. "Taxol: A History of Pharmaceutical Development and Current Pharmaceutical Concerns." J. Natl Cancer Inst Monographs (1993) 15: 141-147
	AM	Arbuck, S.G. "Taxol (paclitaxel): Future directions." Annals of Oncology (1994) 5(Suppl 6): S59-S62
	AN	Beijnen, Jos H., et al. "Bioanalysis, Pharmacokinetics, and Pharmacodynamics of the Novel Anticancer Drug Paclitaxel (Taxol)." Sem in Oncology (1994) 21 (5) (Suppl 8 October) 53-62
	AO	Deutsch, H.M., et al. "Synthesis of Congeners and Prodrugs. 3. Water-Soluble Prodrugs of Taxol with Potent Antitumor Activity." J Medicinal Chem (1989) 32: 788-792
	AP	Greenwald, R.B., et al. "Drug Delivery Systems: Water Soluble Taxol 2'-Poly(ethylene) glycol) Ester Prodrugs - Design and <i>in Vivo</i> Effectiveness." J. Medicinal Chem (1996) 39:424-431
↓	AQ	Greenwald, R.B. et al. "Highly Water Soluble Taxol Derivatives: 7-Polyethylene Glycol Carbamates and Carbonates." J Org Chem (1995) 60: 331-336

Continue on page 2

Examiner

Ade Robins

DATE CONSIDERED

10/28/05

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.

FORM PTO-1449			US Dept. of Commerce Patent and Trademark Office		ATTORNEY DOCKET NO: 4012-130 9233-22 DV		SERIAL NO. to be assigned 09/459,443	
INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)			APPLICANT					
			Nnochiri N. Ekwuribe		FILING DATE Concurrently herewith December 13, 1999		GROUP Not Yet Assigned	
U.S. PATENT DOCUMENTS								
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FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	NO
OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)								
	AR	Horwitz, S.B. "TAXOL (paclitaxel): Mechanisms of action." Annals of Oncology (1994) 5 (Suppl.6): S3-S6.						
	AS	Kingston, David G.I. "Taxol: the chemistry and structure-activity relationships of a novel anticancer agent." TIBTECH (June 1994) 12: 222-227						
	AT	Kingston, David G.I. "The chemistry of Taxol." Pharmac Ther (1991) 52: 1-33						
	AU	Kohler, David R., et al. "Paclitaxel (Taxol)." (1994) Pharmacotherapy 14 (1): 3-34						
	AV	Long, Harry J. "Paclitaxel (Taxol): A Novel Anticancer Chemotherapeutic Drug." Mayo Clin Proc (1994) 69: 341-345						
	AW	Parekh, H. et al. "The Transport and Binding of Taxol." Gen Pharmac (1997) 29 (2): 167-172						
	AX	Preston, N.J. "Paclitaxel (Taxol) - a guide to administration." European J of Cancer Care (1996) 5: 147-152						
	AY	Rowinsky, Eric K. et al. "The Clinical Pharmacology and Use of Antimicrotubule Agents in Cancer Chemotherapy." Pharmac Ther (1991) 52: 35-84						
	AZ	Rowinsky, Eric K. et al. "Taxol: The First of the Taxanes, an Important New Class of Antitumor Agents." Seminars in Oncology (1992 Dec) 19(6): 646-662						
	BA	Rowinsky, Eric K. et al. "Taxol: Pharmacology, Metabolism and Clinical Implications." Cancer Surveys (1993) 17: 283-304						
	BB	Straubinger, Robert M. et al. "Novel Taxol Formulations: Taxol-Containing Liposomes." J Nat Cancer Inst Monographs (1993) No.15: 69-78						
	BC	Workman, Paul. "Pharmacokinetics and Cancer: Successes, Failures and Future Prospects." Cancer Surveys (1993) 17: 1-26						
	BD	Delgado et al. "The Uses and Properties of PEG-Linked Proteins". Critical Review in Therapeutic Drug Carrier Systems, 9(3, 4):249-304 (1992).						
Continued on page								
EXAMINER <i>Chloe Rubin</i>							DATE CONSIDERED <i>10/28/05</i>	
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.								

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LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)						10/633,966	
			Applicants: Ekwuribe				
			Filing Date <u>8/4/03</u> concurrently herewith			Group <u>1656</u>	
U. S. PATENT DOCUMENTS							
Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
<u>AK</u>	1.	5,359,030	10/25/94	Ekwuribe	530	303	
	2.	5,438,040	08/01/95	Ekwuribe	514	3	
	3.	5,681,811	10/28/97	Ekwuribe	514	8	
	4.	6,191,105	02/20/01	Ekwuribe et al.	514	3	
	5.	6,309,633	10/31/01	Ekwuribe et al.	424	85.1	
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
<u>AK</u>	6.	WO97/04796	02/13/97	PCT	—	—	
<u>AK</u>	7.	WO97/15671	05/01/97	PCT	—	—	
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
<u>AK</u>	8.	Anderson et al., "Structure-Activity Relationship Assessment of Conjugated Enkephalins in Centrally Mediated Analgesia," <i>Soc. Neurosci. Abstr.</i> , 25(1): 180 (1999).					
	9.	Ekwuribe et al., "Oral Insulin Delivery: Hydrolyzable Amphiphilic Oligomer Conjugates Prolong Glucose Reduction," <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> , 26: 147-148 (1999).					
	10.	Freeman et al., "Interactions of Pancreatic Secretory Trypsin Inhibitor in Small Intestinal Juice: Its Hydrolysis and Protection by Intraluminal Factors," <i>Clinica Chimica Acta</i> , 195: 27-40 (1990).					
	11.	Friedman, J. & Halaas, J., "Leptin and the Regulation of Body Weight in Mammals," <i>Nature</i> , 395: 763-770 (1998).					
	12.	Grant et al., "Development of Neuroendocrine Tumors in the Gastrointestinal Tract of Transgenic Mice. Heterogeneity of Hormone Expression," <i>Am. J. Pathol.</i> , 136(6): 1349-1363 (1990).					
<u>AK</u>	13.	Green, G. & Lyman, R., "Feedback Regulation of Pancreatic Enzyme Secretion as a Mechanism for Trypsin Inhibitor-Induced Hypersecretion in Rats," <i>Proceedings of the Society for Experimental Biology and Medicine</i> , 140(1): 6-12 (1972).					

Joe Ekwuribe

10/28/03

FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office		Attorney Docket Number 9233-22DV	Serial No. to be assigned <i>10/633, 964</i>																																																																								
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Applicants: Ekwuribe																																																																											
Filing Date <i>8/4/03</i>			Group <i>1654</i>																																																																								
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td> <td style="width: 10%; text-align: center;">14.</td> <td colspan="2">Green et al., "Plasma Secretin, CCK, and Pancreatic Secretion in Response to Dietary Fat in the Rat," <i>Am. J. Physiol.</i>, 256: G1016-1021 (1989).</td> </tr> <tr> <td></td> <td style="text-align: center;">15.</td> <td colspan="2">Gary M. Green, "Feedback Inhibition of Cholecystokinin Secretion by Bile Acids and Pancreatic Proteases," <i>Annals New York Academy of Sciences</i>, 713: 167-179 (1994).</td> </tr> <tr> <td></td> <td style="text-align: center;">16.</td> <td colspan="2">Herzig et al., "Diazepam Binding Inhibitor is a Potent Cholecystokinin-Releasing Peptide in the Intestine," <i>Proc. Natl. Acad. Sci. 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	29.	Viktor Mutt, "Secretin and Cholecystokinin," <i>Advances in Metabolic Disorders</i> , 11: 251-320 (1988).																																																																									
	30.	Parlesak et al., "Parallel Determination of Gut Permeability in Man with M, 400, M, 1500, M, 4000 and M, 10 000 Polyethylene Glycol)," <i>Eur. J. Clin. Chem. Clin. Biochem.</i> , 32: 813-820 (1994).																																																																									
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